



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Dr. Birgitte Povlsen, Head
Division for Import and Export
Danish Veterinary and Food Administration
Moerkhoel Bygad 19
DK-2860 Soeborg
Denmark

NOV 15

Dear Dr. Povlsen:

The Food Safety and Inspection Service conducted an on-site audit of Denmark's meat inspection system from March 14 through April 10, 2001. Enclosed is a copy of the final audit report. Denmark's comments on the draft final audit report have been included as an attachment to the enclosed final audit report.

If you have any questions regarding the audit or need additional information, please contact me by telephone at (202) 720-3781 or by fax at (202) 690-4040. I can also be reached by email at sally.stratmoen@usda.gov.

Sincerely,

Sally Stratmoen, Acting Director
International Policy Staff
Office of Policy, Program Development
and Evaluation

Enclosure

cc:

Bente Wantzin, Agriculture Section, Royal Danish Embassy
Mary Revelt, Minister/Counselor for Agricultural Affairs, USEU/Brussels
Gerry Keily, Counselor (Agriculture), EU Mission to the US, Wash, DC
Philip Letarte, Ag Counselor, FAS, U.S. Embassy, Copenhagen
John Wilson, Area Officer, FAS
John Prucha, ADA, OPPDE, FSIS
Amy Winton, State Department
Donald Smart, TSC, FSIS
Karen Stuck, IES, IPS, FSIS
Richard Brown, ES, IPS, FSIS
Country File (FY 2001 -- On-Site Audits file)

FSIS:OPPDE:IPS:ES:RBrown:mm:202-720-6400:11/14/01:Denmark Fnl rpt Ltr 11-01.doc

Clearance:

Sally Stratmoen, Acting Director, ES, FSIS, IPS

Initial

Date



United States
Department of
Agriculture

Food Safety
And Inspection
Service

Technical
Service
Center

Suite 300, Landmark Center
1299 Farnam Street
Omaha, NE 68102

AUDIT REPORT FOR DENMARK

MARCH 14 THROUGH APRIL 10, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Denmark's meat inspection system from March 14 through April 10, 2001. Nine of the 99 establishments certified to export meat to the United States were audited. Six of these were slaughter and processing establishments; two were conducting processing operations, and the remaining establishment was a cold storage facility.

The last audit of the Danish meat inspection system was conducted in September 2000. Nine were audited: seven (Ests. 15, 53, 79, 220, 319, 337, and 469) were acceptable and two (Ests. 28 and 47) were evaluated as acceptable/re-review. The deficiencies reported at that time included inadequacies regarding post-mortem inspection procedures, inadequate documentation of Sanitation Standard Operating Procedures, lack of monthly internal reviews of establishments, non-implementation of the requirement for pre-shipment document reviews, and inadequate light intensity at post-mortem inspection stations.

Beef products were ineligible for export to the U.S. at the time of this audit, due to the presence of Bovine Spongiform Encephalopathy in Europe, and because of the outbreak of Foot and Mouth Disease in Europe shortly before this audit began. Only canned pork products were being accepted from Denmark at U.S. ports of entry.

During the period from January 1 to February 28, 2001, Danish establishments exported 21,195,742 lbs. of pork and pork products to the U.S. Of these products, 7,125,384 lbs. were reinspected at U.S. ports of entry; a total of 98,835 lbs. (slightly less than 1.4%) of the reinspected products were rejected for processing defects (1% of the amount reinspected), pathology (0.24%), transportation damage (0.07%), and missing shipping marks (0.05%). During calendar year 2000, Danish establishments exported 137,170,224 lbs. of pork and pork products to the U.S. Of these products, 39,359,270 lbs. were reinspected at U.S. ports of entry; a total of 387,097 lbs. (slightly less than 1%) of the reinspected products were rejected were for labeling defects (0.25% of the amount reinspected), violative net weight (0.22%), transportation damage (0.14%), processing defects (0.1%), unsound condition (0.09%), missing shipping marks (0.08%), contamination (0.07%), and pathology (0.04%).

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Danish national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the several of the Danish

Veterinary and Food Administration's regional headquarters offices. The third was conducted by on-site visits to establishments. (The two establishments that had been evaluated as acceptable/re-review during the previous audit were visited again; the remainder of the establishments selected for on-site audits and those selected for document audits were chosen randomly.) The fourth part involved visits to four laboratories, one performing analytical testing of field samples for the national residue testing program, and three others culturing field samples for the presence of microbiological contamination with *Salmonella* species and *Escherichia coli* (*E. coli*). One of the latter three was a government laboratory; the other two were private.

Denmark's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials (none of the establishments audited at this time were unacceptable).

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in all nine of the establishments audited; two of these (Ests. 71 and 190) were recommended for re-review. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* species and generic *E. coli*, are discussed later in this report.

As stated above, among the concerns that had been identified during the last audit of the Danish meat inspection system, conducted in September-October 2000, were the following:

1. Inadequacies regarding post-mortem inspection procedures. *The post-mortem inspection procedures were now found to be complete and professionally conducted in all of the six slaughter establishments audited.*
2. Inadequate documentation of Sanitation Standard Operating Procedures in two establishments. *Inadequate documentation was again found in two establishments.*

3. Lack of monthly internal reviews in six establishments. *Considerable improvement in the monthly internal review program had been made.*
4. Non-implementation of the requirement for pre-shipment document reviews. *Pre-shipment document reviews had been implemented in all but one of the establishments visited on-site by the dates of the individual audits.*
5. Inadequate light intensity at post-mortem inspection stations in four of the six slaughter plants visited. *Light was adequate in all slaughter establishments except in the retained carcass inspection areas in two establishments.*

Entrance Meeting

On January 20, an entrance meeting was held in the Mørkhøj offices of the *Danish Veterinary and Food Administration (DVFA)*, and was attended by Dr. Kristian Hermannsen, Asst. Chief Veterinary Officer and head of the Unit for Export Equivalence and Certification; Dr. Birgitte Povlsen, Senior Veterinary Officer and Head of the Division for Import/Export; Dr. Jens Munk Ebbesen, Deputy Chief, Division for Import/Export; Dr. Henning Pedersen, Veterinary Officer, Division for Import/Export; Dr. Justin Ajufo, Veterinary Officer, Division for Food Safety; Dr. Mette Hjulmand-Lassen, Veterinary Officer, Division for Food Safety; Mr. Finn Haunstrup Clemmensen, Head of the Division for Control Coordination; Dr. Mette Espersen, Veterinary Officer, Institute for Food Safety and Toxicology; Mr. Flemming Kærby, M.Sc, Institute for Food Research and Nutrition; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. Topics of discussion included the following:

1. There were changes in the organizational structure. A new organizational chart was presented at the exit meeting.
2. Foot-and-Mouth Disease (FMD) had been confirmed in France the day before this entrance meeting with the Danish officials; the Danes stated that the measures being taken to keep Denmark free of FMD were being published on their Website, at: <http://www.fdir.dk>; link FMD.
3. Details of the itinerary were discussed and finalized.

Headquarters Audit

There had been a few changes in the organizational structure since the last U.S. audit of Denmark's inspection system in September 2000. A new organizational chart was provided.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted audits of inspection system documents pertaining to the establishments listed for records review. These records audits were conducted at the regional office. The records review focused primarily on food safety hazards and included the following:

- Monthly internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing, and *Salmonella* testing.
- Export product inspection and control.

No concerns arose as a result the examination of these documents.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Denmark as eligible to export meat products to the United States were full-time DVFA employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Ninety-nine establishments were certified to export meat products to the United States at the time this audit was conducted. Nine establishments were visited for on-site audits. In all of the establishments visited, except as noted below, both DVFA inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories; intra-laboratory quality assurance procedures, including sample handling; and methodology.

The Fødevareregion Aarhus Laboratory in Aarhus was audited on March 23, 2001. Effective controls were in place for sample handling, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

The check sample program was designed to fulfill European Commission requirements. Intra-laboratory check samples were not being performed in this laboratory. International check samples were provided by FAPAS in England and had been performed in April and October 2000 for organochlorines and were scheduled for June and October 2001; the schedule also called for two check samples each for trace elements for April, July, and November 2001.

A new method for organochlorine pesticides and PCBs had just recently been developed, and the sampling requests had just been distributed at the end of February. Note: all the planned analyses for CY 2000 had been completed.

The sampling for trace elements was just getting underway. Previously two other laboratories were also performing the analyses for these; this laboratory will now undertake the entire country's testing for trace elements. Note: Arsenic was not part of the sampling plan at the moment; new equipment was acquired five months previously and optimization was still ongoing. Current sampling was for lead, mercury, cadmium, and selenium.

The quality control system did not include the documentation of the preparation of fresh standard solutions in a bound notebook with previously numbered pages. The laboratory officials agreed to correct this.

Denmark's microbiological testing for *Salmonella* was being performed in both private and government laboratories. One government laboratory (the Laboratory of Fødevareregion Sønderjylland, in Haderslev) and two private laboratories, situated in the Danish Crown slaughter establishments in Horsens and Saeby, were audited. The auditor determined that the system met the criteria established for the use of private laboratories under FSIS's Pathogen Reduction/HACCP rule. These criteria are:

1. The laboratories have been accredited/approved by the government, accredited by third party accrediting organization with oversight by the government, or a government contract laboratory.
2. The laboratories have properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
3. Results of analyses are being reported to the government or simultaneously to the government and establishment.

Establishment Operations by Establishment Number

The following operations were being conducted in the nine establishments:

Cold storage – Est. 165

Swine slaughter and pork cutting – Est. 91

Pork cutting, boning, and packaging – Est. 339

Swine slaughter, cutting, and curing – Est. 28
Beef and pork cutting and cold storage – Est. 190
Swine slaughter, cutting, boning, and curing – Est. 71
Swine slaughter, boning, cutting, curing, sausages, and hams (retort pouch, not-shelf stable) – Est. 25
Swine slaughter, cutting, boning, cooked and uncooked pork loin back ribs, spareribs, and cooked bones – Est. 38
Swine and beef slaughter; pork and beef cutting and cooked sausage production and occasional curing of ham and pork backs – Est. 47

SANITATION CONTROLS

Based on the on-site audits of establishments, Denmark's inspection system had controls in place for water potability; chlorination procedures; back-siphonage prevention; temperature; operations and inspectors' work space; ventilation; over-product ceilings and equipment; dry storage areas; ante-mortem facilities; welfare facilities; outside premises; personal dress, habits, and hygiene procedures; product transportation; maintenance; and waste disposal.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs in the establishments visited were found to meet the basic FSIS regulatory requirements, with the exception of documentation in four of them.

In Est. 25, heavy, dripping condensation was observed directly over exposed carcasses in numerous areas in the coolers during the audit. A review of the establishment's documentation revealed no mention of any condensation problems or corrective actions. The in-plant inspection service personnel were verifying the establishment's documentation of SSOPs approximately monthly: No condensation problems had been noted during January or February 2001.

In Est. 71, heavy, dripping condensation was observed directly over clean containers ready for use in one large boning area. A review of the establishment's documentation revealed no mention of any operational condensation problems or corrective actions since February 1, 2001. The in-plant inspection service personnel were verifying the establishment's documentation of SSOPs approximately weekly; lack of the establishment's documentation of condensation problems had been noted.

In Ests. 91 and 190, there was documentation of sanitation activities, but it was in need of improvement.

The importance of documentation of pre-operational and operational sanitation activities, findings, and corrective actions was stressed both in the meetings in the individual establishments and during the exit meeting with Danish officials. Assurances were given that improvements would be implemented promptly.

The following sanitation deficiencies were also identified:

Product Handling and Storage

1. In Est. 25, exposed product was stored directly below heavy, dripping condensation on cooling units in several areas of the (extensive) carcass coolers. DVFA officials ordered complete reinspection and trimming, as necessary, of all affected product, development of a program for improved monitoring and documentation of condensation control, and rejected the affected rails pending elimination of the cause.
2. In Est. 71, a stack of edible containers, ready for use, was stored under an area of heavy condensation on the ceiling in the corner of one large cutting room. The establishment sent the containers for re-cleaning, but later in the review another piece of equipment used for transporting edible containers was found to be stored in the same location. The area was rejected for personnel- and product-contact equipment traffic.
3. In Est. 190, exposed product was stored directly underneath rusty overhead structures in a cooler. Cleaning and painting were scheduled and measures were put in place to prevent storage of product under the area in question.

Cross-Contamination

1. In Est. 38, several swine carcass heads were observed contacting an inedible container at the station where stick wounds were trimmed. Corrective action by management was immediate.
2. In Est. 91, a floor-cleaning employee contaminated two edible product containers and two hams. The Veterinarian-In-Charge ordered cleaning of the edible product containers and trimming of the contaminated product.

Sanitizers

1. Sanitizing facilities for the splitting saws used at the retained inspection area in Est. 91 were inadequate. The DVFA official ordered prompt installation of an adequate sanitizer. Three sanitizers on the slaughter floor, at trim stations after the post-mortem inspection, were below the required temperatures. The establishment General Director took immediate corrective action.
2. In Est. 71, there was no sanitizer in the pre-boning trim area. The DVFA officials ordered immediate correction.

Personnel Hygiene and Practices

1. An edible-product worker in Est. 38 failed to wash his hands and change his gloves after contaminating them through contact with a piece of meat that had fallen onto the floor. The management official ensured that he washed his hands and changed gloves.
2. An edible-product worker in Est. 71 was observed to contaminate his hands on an inedible container and not wash his hands before returning to work. The DVFA officials took immediate corrective action.
3. Three workers in the boning room in Est. 190 did not wash their hands when returning from a break. Another worker hung his apron on a wall hook intended for storage of, and in contact with, a shovel used for meat that had fallen on the floor. The establishment official took immediate corrective actions.
4. Several workers in Est. 339 were observed to contaminate their aprons through contact with an inedible container in the receiving area. DVFA officials took immediate corrective actions.

Product-Contact Equipment

1. Several stainless steel combo bins in Est. 28 had cracked and torn corners. These were retained by the Veterinarian-In-Charge for repair or replacement.
2. Inadequately cleaned plastic containers were ready for use in one production area of Est. 91. Corrective action was taken immediately by the inspection personnel.
3. An obvious grease spot on a cutting board was ignored by a worker returning from a break in Est. 190. DVFA officials ordered immediate cleaning and disinfection.

Over-Product Equipment

1. Maintenance of over-product structures had been neglected in a few areas in Est. 25: Mold was observed on the edges of skylights, mold and old product residues on hoist controls, and old product residues on rail gate switch handles. Management officials agreed to conduct a thorough inspection and take corrective actions as necessary.
2. In Est. 38, old product residues were found on rail gates in the main cutting room. The management officials initiated immediate corrective actions, and DVFA officials ordered increased maintenance and pre-operational monitoring.
3. Heavy rust, flaking paint, and heavy, dried and flaking grease were observed on over-product equipment in the pre-boning trim area in Est. 71. Management officials agreed to clean the area promptly.

4. Rust was present in Est. 190 on overhead structures in a cooler, with exposed product stored directly underneath. Cleaning and painting were scheduled and measures were put in place to prevent storage of product under the area in question.

Dry Storage Areas

1. Heavy dust buildup was found on many sacks and other containers of non-meat ingredients in the dry storage area in Est. 25; also, detritus and live spiders were present in inaccessible spaces between racks and walls. DVFA officials ordered (1) a prompt, thorough cleaning regimen, to begin before the next day's production, (2) inspection by processing personnel of all non-meat ingredients from the area before use in production, and (3) development of a reliable cleaning and maintenance program, including moving racks to enable cleaning behind them.
2. Dead insects and spider webs were in evidence on slanting windowsills above stored packaging materials. The management official ordered the room to be thoroughly cleaned before the next day's production.

Other Sanitation Deficiencies in Individual Establishments

1. The dropped-meat reconditioning procedure in Est. 190, as demonstrated, was unacceptable, resulting in gross contamination of the meat to be trimmed and of the work surface on which the procedure was performed. The knife was not sanitized after being contaminated. The DVFA internal reviewer who was leading the audit stopped the procedure, condemned the meat, and ordered termination of dropped-meat reconditioning until such time as the establishment could demonstrate to DVFA the capability of performing the procedure in a sanitary manner.
2. There were no hand-washing facilities in one production area in Est. 25. DVFA officials ordered prompt correction.
3. In Est. 28, several doors between production areas and outside premises were left open during operations. Corrective actions by the establishment management officials were immediate, and the Veterinarian-In-Charge ordered implementation of an improved policy.

ANIMAL DISEASE CONTROLS

Denmark's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned product. There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

During the months preceding this audit, Foot-and Mouth Disease had broken out in England, Northern Ireland, the Republic of Ireland, the Netherlands, and France. The Danish officials had devoted considerable effort to keeping Denmark free of the disease. An up-to-date report on the status of these controls is available through the Website: <http://www.fdir.dk>; link FMD.

RESIDUE CONTROLS

Denmark's National Residue Testing Plan for 2000 was being followed, and was on schedule. The Danish inspection system had adequate controls in place to ensure compliance with residue sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

The Danish inspection system had controls in place to ensure adequate humane handling and slaughter, ingredients identification, formulations, packaging materials, laboratory confirmation, label approvals, inspector monitoring, processing equipment and records, empty can inspection filling procedures, container closure exam, interim and post-processing handling, incubation procedures, processing defect actions by establishment personnel, and processing control by inspection personnel..

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements, with the following exceptions:

1. In all but one (Est. 190) of the establishments audited on-site, pre-shipment document reviews had been developed and implemented by the time of the individual audits. Of the sixteen establishments selected for document reviews, no pre-shipment document reviews had as yet been developed and implemented in nine (Ests. 29, 30, 31, 53, 65, 95, 211, 260, and 417). Considerable work had gone into the fulfillment of this requirement since the previous FSIS audit, and the DVFA officials gave assurances that it would be universally in place in all establishments certified to produce products eligible for export to the United States within a very short time.
2. There was a Critical Control Point in Est. 71 for cooler temperatures. A review of the documentation revealed that there was consistent documentation for the temperatures, but documentation of corrective actions when critical limits were exceeded was inadequate.

3. No procedures to verify that the HACCP plan was being effectively implemented and functioning as designed had been developed and implemented in Est. 190. The FSIS auditor discussed the requirement both in the establishment and during the exit meeting in Copenhagen, and the DVFA officials gave assurances the requirement would be promptly met.

Testing for Generic *E. coli*

Six of the establishments audited on-site and five of those selected for document review were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

Denmark had adopted the FSIS regulatory requirements for generic *E. coli* testing with the exception of the following different equivalent requirements:

1. SAMPLING TOOLS

- Denmark was using a gauze swab sampling tool. The gauze swab is a generally/internationally recognized sample collection tool for *E. coli* on meat or poultry product surfaces.
- The sampling tool is sensitive enough to gather *E. coli* that are present at the sample sites.
- The sampling tool does not contaminate the surfaces of the carcass.

2. ANALYTICAL METHODS: different methods.

- Denmark was using an NMKL method to analyze for generic *E. coli*. This method is a quantitative method of analysis.
- The method is approved by the AOAC International or an internationally recognized scientific organization.

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements.

Additionally, establishments had adequate controls in place to prevent meat products intended for Danish domestic consumption from being commingled with products eligible for export to the United States.

ENFORCEMENT CONTROLS

Inspection System Controls

The DVFA inspection system controls [animal identification, ante-and post-mortem inspection dispositions, control of restricted product and inspection samples, condemned and restricted product control, control of restricted product and inspection samples, boneless meat reinspection, control and disposition of dead, dying, diseased or disabled animals, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans—see the exception noted above for Est. 71), inspection supervision and documentation,] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

No meat imported from other countries, or meat from live animals imported from other countries, was used in any product eligible for export to the United States.

Testing for *Salmonella* Species

Six of the establishments audited on-site and five of those selected for document review were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Denmark had adopted the FSIS regulatory requirements for *Salmonella* testing with the exception of the following equivalent measures:

1. SAMPLE COLLECTOR: establishments take samples.

- The government of Denmark provides a clearly written sampling plan with instructions for sample collection and processing that is followed by all applicable export establishments.
- All applicable veterinarians are properly and uniformly trained; they train the establishment employees. The trained veterinarian observes the collection/storage/transport procedures on a periodic, unannounced basis to ensure that FSIS requirements are met. The government ensures that establishment sample collection activities are appropriate. Sample verification is performed upon request by the DVFA where the official veterinarian collects samples and DVFA analyzes the sample.

- The government of Denmark uses the test results to monitor establishment performance over time.
- The government of Denmark takes immediate action any time an establishment fails to meet *Salmonella* performance standards.

2. LABORATORIES: private laboratories analyze samples.

- The laboratories are independent non-government or establishment laboratories that are accredited by the government of Denmark. The laboratories are required to participate in performance testing to ensure laboratory analyses are properly performed. Establishment labs are under the direct supervision of the on-site veterinarian.
- All accredited laboratories have a formal program to ensure that lab personnel are properly trained, there are suitable facilities and equipment, there is a written quality assurance program, and there are adequate reporting and record keeping facilities.
- Test results are provided directly to the government veterinarian.

3. SALMONELLA TESTING STRATEGY.

- Denmark uses a continuous, ongoing sampling program to determine when to initiate additional *Salmonella* testing. The sampling methodology is based on a uniform system approach in all applicable export establishments. All U.S. export establishments are included in the sample pool. Denmark collects one sample per production day, grouped in sample sets of 55 samples (swine) and uses FSIS Performance Standards and enforcement procedures.
- Denmark uses a continuous, ongoing sampling program to determine when to initiate additional *Salmonella* testing. All products for which there is a U.S. performance standard are included in the sample pool.
- Denmark's testing program has statistical criteria for evaluating test results.
- The percentage of *Salmonella* positives over time meets the FSIS percentage of positives in the FSIS standard.

4. SAMPLING TOOLS.

- The gauze pad sampling tool is used. This sampling tool is internationally recognized for sampling *Salmonella* on meat or poultry product surfaces.
- The sampling tool is sensitive enough to gather *Salmonella* that are present at the sample sites.

- The sampling tool does not contaminate the surfaces of the carcass.

Furthermore, the official veterinarian in each slaughter establishment takes an independent sample once weekly for *Salmonella* analysis. These official samples serve as verification of those taken by the establishments, and are analyzed at an official laboratory.

The *Salmonella* testing programs were found to meet the basic FSIS regulatory requirements.

Species Verification Testing

At the time of this audit, Denmark was not exempt from the species verification requirement. The auditor verified that species verification was being conducted in accordance with FSIS requirements.

Monthly Reviews

FSIS requires documented supervisory visits by a representative of the foreign inspection system to each establishment certified as eligible to export to the United States, not less frequently than one such visit per month, during any period when the establishment is engaged in producing products that could be used for exportation to the United States.

The systems in place for the completion of, and the responsibility for, the monthly reviews was found to vary considerably between the meat inspection regions:

In the region of **Ringsted**, which had five establishments listed for U.S.-export, the monthly internal reviews were being conducted by the Veterinarians-In-Charge at other U.S.-listed establishments in the region. The Head of the regional office of the Food Inspection Service in Ringsted designated which veterinarians were to have this responsibility. These internal auditors submitted copies of their reports to the regional offices for review.

In the region of **Fyn**, there was a designated individual who performed the monthly reviews of the five establishments certified for U.S. export (29, 45, 175, 187, and 198).

In the region of **Sønderjylland**, no one had been specifically assigned the duty of performing the monthly supervisory reviews during the first four months of 2000. As of May 2000, the Chief Veterinarians in the two slaughterhouses in the region had the responsibility to conduct the monthly reviews in the region, and were assigned this duty by the head of the regional office of DVFA.

In the region of **Esbjerg**, before January 1, 2001, the Veterinarians-In-Charge at the two U.S.-certified slaughter plants (Ests. 53 and 340) conducted the monthly internal reviews of each other's assigned establishments, and the inspectors assigned to the other four plants were conducting the monthly reviews of the establishments to which they were assigned, assisted, on occasion, by officials from the regional office. Since January 1, 2001, the Veterinarians-In-Charge at Ests. 53 and 340 have continued to conduct the

monthly internal reviews of each others' assigned establishments, and two officials from the regional office now participate in these duties: One of them and one of the Veterinarians-In-Charge at either Ests. 53 or Est. 340, as a team of two, had conducted the monthly internal reviews of the other four plants certified for US-export.

In the region of *Aarhus*, as of January 1, 2001, one veterinarian from the regional office had had the assignment of performing the internal reviews of the establishment certified to export to the U.S. He had been assisted in some of these internal reviews by the Veterinarian-In-Charge of Establishment 220 in Brabrand and also by two other veterinarians from the regional office.

In the region of *Vejle*, there were 11 establishments listed for U.S. export. Four of the Veterinarians-In-Charge participated in the monthly internal review process, conducting the reviews of establishments other than those in which they were stationed, and the reviews of any given establishment were performed, in different months, by different reviewers. The reviewers' reports were submitted to a supervisor, who was based in the regional office in Vejle. He evaluated the contents of the reports and discussed the findings with the reviewing officers.

In the region of *Herning*, the internal reviews of the eight establishments certified for U.S. export were conducted by six Veterinarians-In-Charge of these establishments. An internal review of an establishment was never conducted by the Veterinarian-In-Charge of that establishment. The reviewers' reports were submitted to a supervisor, who was based in the regional office in Herning. She reviewed the contents of the reports and discussed the findings with the reviewing officers. Starting April 1, 2001, two veterinarians employed in the regional office in Herning will assume the responsibility for the monthly internal reviews; the Veterinarians-In-Charge who were doing this at the time of this audit will then continue to review, on a quarterly basis, the quality control systems in plants other than those in which they are stationed.

In the region of *Viborg*, the monthly internal reviews of the eleven establishments certified for U.S. export were conducted by four Veterinarians-In-Charge and one Deputy Veterinarian-In-Charge of three of these establishments. An internal review of an establishment was never conducted by the VIC in that establishment. The reviewers' reports were submitted to a supervisor, who was based in the regional office in Herning. She reviewed the contents of the reports and discussed the findings with the reviewing officers.

In the region of *Nordjylland*, under the system in place at the time of the audit, the monthly internal reviews of the four slaughter establishments certified for U.S. export (Ests. 13, 28, 62, and 71) were being conducted by the Veterinarians-In-Charge of these establishments. An internal review of an establishment was never conducted by the VIC in that establishment. The Veterinarians-In-Charge of the other eleven (non-slaughter) establishments certified for U.S. export were conducting the internal reviews of the establishments in which they were stationed. Note: only three of these (211, 337, and

469) had exported any products to the U.S. during CY 2000. Starting on May 1, 2001, the VIC in each of the four slaughter establishments was to assume responsibility for supervision of the activities in several of the eleven smaller plants; however, the internal reviews of each of these smaller plants was to be conducted by the Veterinarian-In-Charge who supervised a different set of small plants.

The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the offices of the Regional Authorities.

During the period since the previous FSIS audit, internal reviews were conducted each month at eighteen of the establishments audited. The Auditor examined the internal review reports for the establishments selected both for on-site audits and for document audits, and determined that the supervisory visits had been missed for one month in five establishments and for two months in two establishments. (This represented a considerable improvement in the internal reviews compared to the previous FSIS audit, during which it had been determined that internal reviews were conducted each month at only three of the twenty establishments audited.) The requirement that the internal reviews are to be performed each month when U.S.-eligible production is conducted was emphasized during the meetings with inspection personnel both in the field and in the exit meeting in Copenhagen. The DVFA officials gave assurances that they were aware of the requirement and would ensure that they would be conducted on a monthly basis, at a minimum.

Enforcement Activities

The Danish Veterinary and Food Administration publishes an extensive summary of the Agency's enforcement activities in the form of a compliance report on their Website. This report is very similar in scope and content to the Quarterly Enforcement Report published on FSIS's Website.

Exit Meetings

An exit meeting was conducted in Copenhagen on April 10. The Danish participants were Dr. Birgitte Povlsen, Senior Veterinary Officer and Head of the Division for Import/Export; Dr. Jens Munk Ebbesen, Deputy Chief, Division for Import/Export; Dr. Henning Pedersen, Veterinary Officer, Division for Import/Export; Mr. Flemming Kærby, M.Sc, institute for Food Research and Nutrition; Ms. Susann Jensen, Food Scientist, Division of Food Safety; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. The findings encountered in the course of the audits were discussed and the DVFA officials gave assurances that:

1. Improvements would be implemented promptly in those establishments in which the documentation of pre-operational and operational sanitation activities, findings, and corrective actions had been found deficient.
2. Implementation of pre-shipment document reviews would be mandated in the remaining establishments certified as eligible to produce U.S.-eligible products.

3. Increased attention would be devoted to the monitoring of condensation controls in Establishments 25 and 71.
4. The installation of the necessary sanitizers in Ests. 1 and 91 would be ensured.
5. Effective improvements in the maintenance and cleaning of over-product equipment would be implemented in Ests. 25, 38, 71, and 190.
6. Documented internal reviews of all establishments would be conducted during all months in which production of U.S.-eligible product takes place.

CONCLUSION

The inspection system of Denmark was found to have effective controls in place, or adequate corrective actions were taken, to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Nine establishments were audited on-site: seven were acceptable and two were evaluated as acceptable/re-review. All deficiencies encountered during the on-site establishment audits were adequately addressed to the Auditor's satisfaction

Dr. Gary D. Bolstad
International Audit Staff Officer

(signed) Dr. Gary Bolstad

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing
- D. Data collection instrument for *Salmonella* testing
- E. Laboratory audit form
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report (when it becomes available)

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of the documentation audited from the following establishments that were visited on-site were as follows:

	1	2	3	4	5	6	7	8
25	√	√	√	√	√	√	Inadeq.	√
28	√	√	√	√	√	√	√	√
38	√	√	√	√	√	√	√	√
47	√	√	√	√	√	√	√	√
71	√	√	√	√	√	√	Inadeq.	√
91	√	√	√	√	√	√	√*	√
165	√	√	√	√	√	√	√	√
190	√	√	√	√	√	√	√*	√
339	√	√	√	√	√	√	√	√

25 -- Heavy, dripping condensation was observed directly over exposed carcasses in numerous areas in the coolers during the audit. A review of the establishment's documentation revealed no mention of any condensation problems or corrective actions. The in-plant inspection service personnel were verifying the establishment's documentation of SSOPs approximately monthly: No condensation problems had been noted during January or February 2001.

71 -- Heavy, dripping condensation was observed directly over clean containers ready for use in one large boning area. A review of the establishment's documentation revealed no mention of any operational condensation problems or corrective actions since February 1, 2001. The in-plant inspection service personnel were verifying the establishment's documentation of SSOPs approximately weekly; lack of the establishment's documentation of condensation problems had been noted.

91, 190 – There was documentation, but it was in need of improvement.

Documentation was also audited from the following establishments that were not visited on-site:

	1	2	3	4	5	6	7	8
29	√	√	√	√	√	√	√*	√
30	√	√	√	√	√	√	√*	√
31	√	√	√	√	√	√	√	√
53	√	√	√	√	√	√	√*	√
65	√	√	√	√	√	√	√*	√
85	√	√	√	√	√	√	√	√
95	√	√	√	√	√	√	√	√
161	√	√	√	N/A*	√	√	√	√
177	√	√	√	N/A*	√	√	√*	√
178	√	√	√	√	√	√	√*	√
188	√	√	√	√	√	√	√	√
211	√	√	√	√	√	√	√	√
260	√	√	√	√	√	√	√	√
337	√	√	√	√	√	√	√	√
340	√	√	√	√	√	√	√*	√
417	√	√	√	√	√	√	√*	√

Column 7: The DVFA inspection officials gave assurances that the establishments' documentation was performed as required.

65 Establishment documentation of sanitation had improved, according to the inspection personnel; but documentation of DVFA monitoring of the establishment's fulfilling of its responsibilities, meeting target dates, etc. was in need of improvement.

161 This was strictly a cold storage facility

177 This was strictly a cold-store facility. There were no product-contact surfaces.

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing and documenting pre-shipment document reviews as required.

The results of the documentation audited from the following establishments that were visited on-site were as follows:

Est. #	1. Flow diagram	2. Haz. analysis –all ID'ed	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. procedures	10. Adequate documentation	11. Dated and signed	12. Pre-shipment doc. reviews
25	√	√	√	√	√	√	√	√	√	√	√	√*
28	√	√	√	√	√	√	√	√	√	√	√	√
38	√	√	√	√	√	√	√	√	√	√	√	√*
47	√	√	√	√	√	√	√	√	√	√	√	√
71	√	√	√	√	√	√	√	√	√	Inad.	√	√
91	√	√	√	√	√	√	√	√	√	√	√	N/A*
165	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
190	√	√	√	√	√	√	√*	√	no	√	√	no
339	√	√	√	√	√	√	√	√	√	√	√	√

25 – Pre-shipment document reviews were being conducted, but only since 3/12/01 (3 days prior to this audit).

38 – Pre-shipment document reviews were being conducted, but only since 3/28/01 (1 day prior to this audit).

71—There was documentation for the temperatures in the coolers, but documentation of corrective actions when critical limits were exceeded was inadequate.

91 – Product from Est. 91 was not yet U.S.-eligible. A Pre-shipment Document Review form was being developed.

190 – There was some documentation, but improvement was needed.

Documentation was also audited from the following establishments that were not visited on-site:

Est. #	1. Flow diagram	2. Haz. analysis –all ID'ed	3. Use & users included	4. Plan for each product	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. Procedures	10. Adequate documentation	11. Dated and signed	12. Pre-shipment doc. reviews
29	√	√	√	√	√	√	√	√	√	√	√	no*
30	√	√	√	√	√	√	√	√	√	√*	√	no
31	√	√	√	√	√	√	√	√	√	√	√	no*
53	√	√	√	√	√	√	√	√	√	√	√	no
65	√	√	√	√	√	√	√	√	√	√*	√	no
85	√	√	√	√	√	√	√	√	√	√	√	√
95	√	√	√	√	√	√	√	√	√	√	√	no*
161	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
177	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
178	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
188	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
211	√	√	√	√	√	√	√	√	√	√*	√	no
260	√	√	√	√	√	√	√	√	√	√	√	no
337	√	√	√	√	√	√	√	√	√	√	√	√
340	√	√	√	√	√	√	√	√	√	√	√	√*
417	√	√	√	√	√	√	√	√	√	√	√	no*

29, 31, 95—A document for Pre-Shipment Document Reviews had been developed by Danish Crown and provided to the Veterinarian-In-Charge for comments and was available in the documents provided for audit, but its use had not yet been implemented.

30—The Vet-In-Charge reported that the establishment tended to be lax in documentation of corrective actions, but that he had taken steps to assure improvement.

211—The Vet-In-Charge had identified that the establishment tended to be lax in documentation of the monitoring of some critical limits, but she had taken steps to assure improvement.

65—Establishment documentation was adequate, but there was practically no documentation of inspection oversight of the establishment's fulfilling of its HACCP requirements.

340—Pre-Shipment Document Reviews were implemented 3/15/01.

417—This was strictly a casings operation.

Data Collection Instrument for Generic *E. coli* Testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is/are being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

The results of the documentation audited from the following establishments that were visited on-site were as follows:

Est. #	1. Written procedure	2. Sampler designated	3. Sampling location given	4. Predominant species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
25	√	√	√	√	√	√	√	√	√	√
28	√	√	√	√	√	√	√	√	√	√
38	√	√	√	√	√	√	√	√	√	√
47	√	√	√	√	√	√	√	√	√	√
71	√	√	√	√	√	√	√	√	√	√
91	√	√	√	√	√	√	√	√	√	√
165	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
190	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
339	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Documentation was also audited from the following establishments that were not visited on-site:

Est. #	1. Written procedure	2. Sampler designated	3. Sampling location given	4. Predominant species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
29	√	√	√	√	√	√	√	√	√	√
30	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
31	√	√	√	√	√	√	√	√	√	√
53	√	√	√	√	√	√	√	√	√	√
65	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
85	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
95	√	√	√	√	√	√	√	√	√	√
161	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
177	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
178	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
188	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
211	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
260	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
337	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
340	√	√	√	√	√	√	√	√	√	√
417	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

31 *The rails were chosen at random; carcasses at the ends of the rails were sampled. The other half of the same carcass was used for Salmonella testing.*

Data Collection Instrument for *Salmonella* testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of the documentation audited from the following establishments that were visited on-site were as follows:

Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
25	√	√	N/A	√	√	N/A
28	√	√	N/A	√	√	N/A
38	√	√	N/A	√	√	N/A
47	√	√	N/A	√	√	N/A
71	√	√	N/A	√	√	N/A
91	√	√	N/A	√	√	√
165	N/A	N/A	N/A	N/A	N/A	N/A
190	N/A	N/A	N/A	N/A	N/A	N/A
339	N/A	N/A	N/A	N/A	N/A	N/A

Attachment D-2

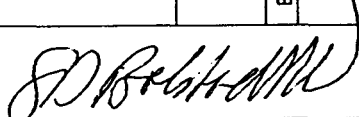
Documentation was also audited from the following establishments that were not visited on-site.

Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
29	√	√	N/A	√	√	N/A
30	√	N/A	√	√	√	N/A
31	√	√	N/A	√	√	N/A
53	√	√	N/A	√	√	N/A
65	N/A	N/A	N/A	N/A	N/A	N/A
85	N/A	N/A	N/A	N/A	N/A	N/A
95	√	√	N/A	√	√	N/A
161	N/A	N/A	N/A	N/A	N/A	N/A
177	N/A	N/A	N/A	N/A	N/A	N/A
178	N/A	N/A	N/A	N/A	N/A	N/A
188	N/A	N/A	N/A	N/A	N/A	N/A
211	N/A	N/A	N/A	N/A	N/A	N/A
260	√	N/A	√	√	√	N/A
337	N/A	N/A	N/A	N/A	N/A	N/A
340	√	√	N/A	√	√	N/A
417	N/A	N/A	N/A	N/A	N/A	N/A

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE 3/23/01	NAME OF FOREIGN LABORATORY Foedevareregion Aarhus Laboratory
FOREIGN COUNTRY LABORATORY REVIEW			
FOREIGN GOV'T AGENCY Danish Veterinary and Food Administration		CITY & COUNTRY Aarhus, Denmark	ADDRESS OF LABORATORY Goeteborgallee 1
NAME OF REVIEWER Dr. Gary D. Bolstad		NAME OF FOREIGN OFFICIAL Dr. Jens Munk Ebbesen; Dr. Inge Emborg	

Residue Code/Name			OC	pcb	TE										
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE												
	Sample Handling	01		A	A	A									
	Sampling Frequency	02		C	C	C									
	Timely Analyses	03		A	A	A									
	Compositing Procedure	04		O	O	O									
	Interpret Comp Data	05		O	O	O									
	Data Reporting	06		A	A	A									
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A									
	Correct Tissue(s)	08		A	A	Musc									
	Equipment Operation	09		A	A	A									
	Instrument Printouts	10		A	A	A									
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	A									
	Recovery Frequency	12		A	A	A									
	Percent Recovery	13		A	A	A									
	Check Sample Frequency	14		C	C	C									
	All analyst w/Check Samples	15		A	A	A									
	Corrective Actions	16		A	A	A									
	International Check Samples	17		A	A	A									
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	C	C	O									
OTHER REVIEW		19	EVAL. CODE												
		20													

SIGNATURE OF REVIEWER



DATE

3/23/01

FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE 3/23/01	NAME OF FOREIGN LABORATORY Foedevareregion Aarhus Laboratory
FOREIGN GOV'T AGENCY Danish Veterinary and Food Administration		CITY & COUNTRY Aarhus, Denmark	ADDRESS OF LABORATORY Goeteborgallee 1
NAME OF REVIEWER Dr. Gary D. Bolstad		NAME OF FOREIGN OFFICIAL Dr. Jens Munk Ebbesen; Dr. Inge Emborg	
RESIDUE	ITEM	COMMENTS	
OC,PCB	2	A new method for organochlorine pesticides and PCBs had just recently been developed, and the sampling requests had just been distributed at the end of February. Note: all the planned analyses for CY 2000 had been completed.	
TE	2	The sampling for trace elements was just getting underway. Previously two other labs were also performing the analyses for these; this laboratory will now undertake the entire country's testing for traced elements. Note: Arsenic was not part of the sampling plan at the moment; new equipment was acquired 5 months previously and optimization was still ongoing. Current sampling was for lead, mercury, cadmium, and selenium.	
All	14	<p>Intra-laboratory check samples were not being performed in this laboratory. International check samples were provided by FAPAS in England and had been performed in April and October 2000 for organochlorines and were scheduled for June and October 2001; the schedule also called for two check samples each for trace elements for April, July, and November 2001.</p> <p>The quality control system did not include the documentation of the preparation of fresh standard solutions in a bound notebook with previously numbered pages.</p>	



Microbiology Laboratory Audit—March 19, 2001
Auditor: Dr. Gary D. Bolstad

General

Name & location of lab: Laboratory of Fødevareregion Sønderjylland, Haderslev, Denmark

Private or gov't lab? Government

How & when was accreditation obtained? First accredited in October 1993 by Danish Accreditation

How & how often is accreditation maintained? Accreditation criteria are reviewed every 15 months and accreditation is renewed with a full review every 5 years.

When and how is payment for analysis provided? Payment is made by the establishments; they are billed monthly.

Are results released before payment is received? Yes

What are the qualifications of the analyst(s) performing the individual tasks within a method?
The laboratory technicians have all received formal education including specific courses in laboratory technology for 2½ years; this includes one year of OJT. They also participate in continuing education courses every year.

What are the qualifications of the direct supervisor of the analysts? Both have Masters degrees in biology and biochemistry; one has additional advanced training in microbiology.

Methodology for HACCP Salmonella samples (regulatory labs)

Does this lab analyze HACCP Salmonella samples? Routine *Salmonella* testing in Denmark, within the framework of the Pathogen Reduction requirements, is done by the establishments, under DVFA supervision. These field samples are analyzed in several private laboratories in the country. DVFA personnel also take one sample per week in each establishment certified to export to the U.S.; these samples are analyzed in government laboratories; these are verification samples, to verify that the establishments' results are accurate and valid. This audit was performed at one of the government laboratories performing the verification analysis for the region of Sønderjylland.

How are HACCP Salmonella samples received & recorded?. (See above.) They come by express mail with guaranteed next-day delivery; the transit temperature is logged.

Are HACCP Salmonella samples analyzed on the day of receipt? (See above.) Yes

What method(s) is used for HACCP Salmonella samples? NMKL-71 (Nordic Committee on Food Analysis)

Is it a qualitative method (i.e. +/- result)? Yes

Are HACCP ground beef samples analyzed for Salmonella? Yes

What is the size of the ground beef test portion? 25 grams

What buffer (and what volume) is used for:

Sponge samples for Salmonella? BPW

Poultry rinsates for Salmonella? N?A

Salmonella ground beef sample homogenates? 25 gm meat + 225 ml BPW

What is the formulation of the Buffered Peptone Water you use?

Peptone	10.0 g/l
NaCl	5.0 "
Disodium phosphate	3.5 "
Potassium dihydrogen phosphate	1.5 "
pH 7.2 ± 0.2	

What analytical controls are used for Salmonella analyses (i.e. control cultures, etc.)? Both a positive control and a sterile control.

Are they employed for each sample set? Yes

How are HACCP Salmonella results expressed? Detected or Not Detected

How are HACCP Salmonella results recorded?: On a certificate which the lab sends to the Veterinarian-In-Charge in the establishment of origin. A copy is kept at the lab.

How and to whom are HACCP Salmonella results reported? A copy of Not-Detected results is sent to the Veterinarian-In-Charge at the establishment of origin; another copy is kept at the regional DVFA-HQ, which houses the government lab.

Are "check" samples periodically used to test the proficiency of the lab and analysts for Salmonella testing?

1. For individual analysts or for the lab as a whole? No—the last was in November-December 1998 (S. adabraka is used as a positive control with each sample set.)
2. What species/strains are used? See above
3. How many samples are analyzed and how often? See above
4. Are both inoculated and uninoculated samples provided to analysts for the proficiency testing?. See above
5. How many colony-forming units (cfu) per gram are inoculated into the proficiency samples provided to analysts?. See above

Methodology for HACCP generic E. coli samples (in-plant or other private labs)

Does this lab analyze HACCP generic E. coli samples? No



Microbiology Laboratory Audit—March 22, 2001
Auditor: Dr. Gary D. Bolstad

General

Name & location of lab: Danish Crown, Horsens Dept.; Horsens, Denmark

Private or gov't lab? Private. The DVFA officials monitor the operations in the laboratory, including sample receipt from other establishments, daily and also the taking of samples in the establishment. Each week the DVFA officials also take one swab sample and have it analyzed for *Salmonella* in an accredited laboratory in Vejle, some 25 km distant.

How & when was accreditation obtained? Not accredited. Approved by Danish Veterinary and Food Authority.

How & how often is accreditation maintained? See above.

When and how is payment for analysis provided? This laboratory is one of three situated in Danish Crown (DC) establishments, and this lab analyzes samples from other DC plants as well as from its own production. The analyses are paid for by the Danish Crown mother company.

Are results released before payment is received? See above.

What are the qualifications of the analyst(s) performing the individual tasks within a method? All have completed specific courses in laboratory technology.

What are the qualifications of the direct supervisor of the analysts? Has completed specific courses in laboratory technology.

Methodology for HACCP Salmonella samples (regulatory labs)

Does this lab analyze HACCP Salmonella samples? Yes.

How are HACCP Salmonella samples received & recorded? They arrive by express mail, and arrive within one day of sending.

Are HACCP Salmonella samples analyzed on the day of receipt? Yes.

What method(s) is used for HACCP Salmonella samples? Either NMKL-71 (Nordic Committee on Food Analysis) or EIAFOSS (Elisa quick-test) (The latter is more expensive but faster, and is used when more rapid results are desired.)

Is it a qualitative method (i.e. +/- result)? Yes.

Are HACCP ground beef samples analyzed for Salmonella? No.

What is the size of the ground beef test portion? N/A

What buffer (and what volume) is used for:

Sponge samples for Salmonella? 10 ml Buffered Peptone Water; 15 ml more are added in the laboratory.

Poultry rinsates for Salmonella? N/A

Salmonella ground beef sample homogenates? N/A

What is the formulation of the Buffered Peptone Water you use?

Peptone	10.0 g/l
NaCl	5.0 "
Phosphate buffer	10.5

25.5 g of the above diluted to 1 liter; pH 7.2 ± 0.2

What analytical controls are used for Salmonella analyses (i.e. control cultures, etc.)? S. adabraka

Are they employed for each sample set? Yes.

How are HACCP Salmonella results expressed? Detected / not detected

How are HACCP Salmonella results recorded?: The results are listed in a table.

How and to whom are HACCP Salmonella results reported? (1) the establishment management, (2) the DVFA Veterinarian-In-Charge in the establishments, by mail. In the event of positive samples, they are notified by telephone.

Are "check" samples periodically used to test the proficiency of the lab and analysts for Salmonella testing?

1. For individual analysts or for the lab as a whole? For the lab as a whole.
2. What species/strains are used? Samples are provided by the official government laboratory in Ringsted; strains that have been employed are *S. amsterdam* and *pomona*.
3. How many samples are analyzed and how often?. Once per year.
4. Are both inoculated and uninoculated samples provided to analysts for the proficiency testing? Samples have contained *Salmonella* spp., *Yersinia*, *Pseudomonas*, *Streptococcus*, *Staphylococcus*, *Listeria*, *Citrobacter* and *Lactobacillus*.
5. How many colony-forming units (cfu) per gram are inoculated into the proficiency samples provided to analysts? Will provide.

Methodology for HACCP generic *E. coli* samples (in-plant or other private labs)

Does this lab analyze HACCP generic *E. coli* samples? Yes

How are HACCP *E. coli* samples received & recorded? Same as for Salmonella

Are HACCP *E. coli* samples analyzed on the day of receipt? Yes

What method is used for HACCP generic *E. coli* samples? NMLK (see above); 3M Petrifilm

Is it a quantitative method? Yes

What buffer (and what volume) is used for:

E. coli sponge samples? 0.9% physiological saline solution, 10 ml; 15 ml are added when received at the lab.

Poultry rinsates for generic E. coli? N/A

What analytical controls are used? No positive controls are used

Are they employed for each sample set? No controls: Petrifilm is used

How are HACCP E. coli results calculated and/or expressed? CFU/cm²

How are E. coli results recorded:

Data sheets/work sheets? Both in table form and on graphs.

Log books?

How and to whom are HACCP E. coli results reported? (1) the establishment management, (2) the DVFA Veterinarian-In-Charge in the establishments

Are "check" samples periodically used to test the proficiency of the lab and analysts for generic E. coli testing? Yes

1. *For individual analysts or for the lab as a whole?* For the lab as a whole.
2. *What species/strains are used?* Samples have contained an *E. coli* strain from Microbiologics, Cat. Nr. 0483s, St. Cloud, MN, 96303, and also *Salmonella spp.*, *Yersinia*, *Pseudomonas*, *Streptococcus*, *Staphylococcus*, *Listeria*, *Citrobacter* and *Lactobacillus*.
3. *How many samples are analyzed and how often?* Once per year
6. 4. *Are both inoculated and uninoculated samples provided to analysts for the proficiency testing?* Yes.
5. *How many colony-forming units (CFU) per gram are inoculated into the proficiency samples provided to analysts?* 1,000 CFU per gram.



Microbiology Laboratory Audit—April 6, 2001
Auditor: Dr. Gary D. Bolstad

General

Name & location of lab: Danish Crown Saeby; Saeby, Denmark

Private or gov't lab? The DVFA officials monitor the operations in the laboratory, including sample receipt from other establishments, daily and also the taking of samples in the establishment. Each week the DVFA officials also take one swab sample and have it analyzed for *Salmonella* in an accredited laboratory in Aalborg, some 50 km distant.

How & when was accreditation obtained? Not accredited

How & how often is accreditation maintained? See above

When and how is payment for analysis provided? This laboratory is one of three situated in Danish Crown (DC) establishments, and this lab analyzes samples from other DC plants as well as from its own production. The analyses are paid for by the Danish Crown mother company.

Are results released before payment is received? See above.

What are the qualifications of the analyst(s) performing the individual tasks within a method?
All have completed specific courses in laboratory technology.

What are the qualifications of the direct supervisor of the analysts? Has completed specific courses in laboratory technology.

Methodology for HACCP Salmonella samples (regulatory labs)

Does this lab analyze HACCP Salmonella samples? Yes.

How are HACCP Salmonella samples received & recorded? They arrive by express mail, and arrive within one day of sending.

Are HACCP Salmonella samples analyzed on the day of receipt? Yes.

What method(s) is used for HACCP Salmonella samples?

Is it a qualitative method (i.e. +/- result)? Yes.

Are HACCP ground beef samples analyzed for Salmonella? No.

What is the size of the ground beef test portion? See above.

What buffer (and what volume) is used for:

Sponge samples for Salmonella? 10 ml Buffered Peptone Water; 15 ml more are added in the laboratory.

Poultry rinsates for Salmonella? N/A

Salmonella ground beef sample homogenates? N/A

What is the formulation of the Buffered Peptone Water you use?

Peptone	10.0 g/l
NaCl	5.0 "
Disodium phosphate	3.5 "
Potassium dihydrogen phosphate	1.5 "
pH 7.2 ± 0.2	

What analytical controls are used for Salmonella analyses (i.e. control cultures, etc.)? S. adabraka

Are they employed for each sample set? Yes.

How are HACCP Salmonella results expressed? Detected / not detected

How are HACCP Salmonella results recorded? The results are listed in a table.

How and to whom are HACCP Salmonella results reported? (1) the establishment management, (2) the DVFA Veterinarian-In-Charge in the establishments, by mail. In the event of positive samples, they are notified by telephone.

Are "check" samples periodically used to test the proficiency of the lab and analysts for Salmonella testing?

1. For individual analysts or for the lab as a whole? For the lab as a whole.
2. What species/strains are used? Samples are provided by the official government laboratory in Ringsted; strains that have been employed are S. amsterdam and pomona.
3. How many samples are analyzed and how often?. Once per year.
4. Are both inoculated and uninoculated samples provided to analysts for the proficiency testing? Samples have contained Salmonella spp., Yersinia, Pseudomonas, Streptococcus, Staphylococcus, Listeria, Citrobacter and Lactobacillus.
5. How many colony-forming units (cfu) per gram are inoculated into the proficiency samples provided to analysts? Will provide.

Methodology for HACCP generic E. coli samples (in-plant or other private labs)

Does this lab analyze HACCP generic E. coli samples? Yes

How are HACCP E. coli samples received & recorded? Same as for Salmonella

Are HACCP E. coli samples analyzed on the day of receipt? Yes

What method is used for HACCP generic E. coli samples? NMLK (see above); 3M Petrifilm

Is it a quantitative method? Yes

What buffer (and what volume) is used for:

E. coli sponge samples? 0.9% physiological saline solution, 10 ml; 15 ml are added when received at the lab.

Poultry rinsates for generic *E. coli*? N/A

What analytical controls are used? No positive controls are used

Are they employed for each sample set? No controls: Petrifilm is used

How are HACCP *E. coli* results calculated and/or expressed? CFU/cm²

How are *E. coli* results recorded:

Data sheets/work sheets? Both in table form and on graphs.

Log books?

How and to whom are HACCP *E. coli* results reported? By mail, to (1) the establishment management, (2) the DVFA Veterinarian-In-Charge in the establishments

Are "check" samples periodically used to test the proficiency of the lab and analysts for generic *E. coli* testing? Yes

1. For individual analysts or for the lab as a whole? For the lab as a whole.
2. What species/strains are used? Samples have contained *E. coli* VDL 228, *Salmonella* spp., *Yersinia*, *Pseudomonas*, *Streptococcus*, *Staphylococcus*, *Listeria*, *Citrobacter* and *Lactobacillus*.
3. How many samples are analyzed and how often? Once per year
6. 4. Are both inoculated and uninoculated samples provided to analysts for the proficiency testing? Yes.
5. How many colony-forming units (CFU) per gram are inoculated into the proficiency samples provided to analysts? 1,000 CFU per gram.

Att. F-1a

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE 3-15-01	ESTABLISHMENT NO. AND NAME 25 -- Steff-Houlberg		CITY Ringsted
FOREIGN PLANT REVIEW FORM					COUNTRY Denmark
NAME OF REVIEWER Dr. Gary D. Bolstad		NAME OF FOREIGN OFFICIAL Dr. Henning Petersen, Dr. Henning Knudsen		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	
CODES (Give an appropriate code for each review item listed below) A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply					
1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 M	Laboratory confirmation	57 A
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 A
Hand washing facilities	04 M	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 M	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 A
Lighting	11 A	Antemortem inspec. procedures	38 A	Interim container handling	67 A
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 A
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 A
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 M	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas (inside)	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 M	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	SSOPs	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A	HACCP	83 A
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O	COMMENTS MADE ON REVERSE	

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE 3-15-01	ESTABLISHMENT NO. AND NAME 25 -- Steff-Houlberg	CITY Ringsted
			COUNTRY Denmark
NAME OF REVIEWER Dr. Gary D. Bolstad	NAME OF FOREIGN OFFICIAL Dr. Henning Petersen, Dr. Henning Knudsen	EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	

COMMENTS:

04 There were no hand-washing facilities in one production area. DVFA officials ordered prompt correction.

18/30 Heavy, dripping condensation was found on cooling units over exposed product in several areas of the (extensive) carcass coolers. DVFA officials ordered complete reinspection and trimming, as necessary, of all affected product, development of a program for improved monitoring and documentation (see item 82) of condensation control, and rejected the affected rails pending elimination of the cause.

18/33 Maintenance of over-product structures had been neglected in a few areas: Mold was observed on the edges of skylights, mold and old product residues on hoist controls, and old product residues on rail gate switch handles. Management officials agreed to conduct a thorough inspection and take corrective actions as necessary.

21 Heavy dust buildup was found on many sacks and other containers of non-meat ingredients in the dry storage area; also, detritus and live spiders were present in inaccessible spaces between racks and walls. DVFA officials ordered (1) a prompt, thorough cleaning regimen, to begin before the next day's production, (2) inspection by processing personnel of all non-meat ingredients from the area before use in production, and (3) development of a reliable cleaning and maintenance program, including moving racks to enable cleaning behind them.

82 The in-plant inspection service personnel were verifying the establishment's documentation of SSOPs approximately monthly. No condensation problems had been noted in January or February. A review of the establishment's documentation revealed no mention of any condensation problems or corrective actions (heavy, dripping condensation was observed directly over exposed carcasses in numerous areas in the coolers during the audit).

HH. F-2a

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE 4/5/2001	ESTABLISHMENT NO. AND NAME 28 -- Danish Crown Noerresundby		CITY Noerresundby
FOREIGN PLANT REVIEW FORM					COUNTRY Denmar
NAME OF REVIEWER Dr. Gary D. Bolstad		NAME OF FOREIGN OFFICIAL Drs. Birgitte Povlsen, Irma Lahmann, L. Mogstad		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	
CODES (Give an appropriate code for each review item listed below) A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply					
1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 A	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 O
Equipment approval	16 A	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 A	Single standard	75 A
Other product areas (inside)	20 M	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 A	SSOPs	82 A
Personal hygiene practices	26 A	Ingredients identification	53 A	HACCP	83 A
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O	COMMENTS MADE ON REVERSE	

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE 4/5/2001	ESTABLISHMENT NO. AND NAME 28 -- Danish Crown Noerresundby	CITY Noerresundby	
	COUNTRY Denmar			
NAME OF REVIEWER Dr. Gary D. Bolstad	NAME OF FOREIGN OFFICIAL Drs. Birgitte Povlsen, Irma Lahmann, L. Mogstad		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	

COMMENTS:

19 Several stainless steel combo bims had cracked and torn corners. These were retained by the Veterinarian-In-Charge for repair or replacement.

20 Several doors between production areas and outside premises were left open during operations. Corrective actions by the establishment management officials were immediate and the Veterinarian-In-Charge ordered implementation of an improved policy.

AF-3a

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE 3/29/01	ESTABLISHMENT NO. AND NAME 38 -- Danish Crown Struer		CITY Struer
FOREIGN PLANT REVIEW FORM					COUNTRY Denmark
NAME OF REVIEWER Dr. Gary D. Bolstad		NAME OF FOREIGN OFFICIAL Drs.J.M.Ebbesen, Henni Lybye, N.O.Bjerregaard		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	
CODES (Give an appropriate code for each review item listed below) A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply					
1. CONTAMINATION CONTROL		Cross contamination prevention	28 M	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 M	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 A	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 O
Equipment approval	16 A	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 M	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas (inside)	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 A	SSOPs	82 A
Personal hygiene practices	26 M	Ingredients identification	53 O	HACCP	83 A
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O	COMMENTS MADE ON REVERSE	

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE 3/29/01	ESTABLISHMENT NO. AND NAME 38 -- Danish Crown Struer	CITY Struer
			COUNTRY Denmark
NAME OF REVIEWER Dr. Gary D. Bolstad	NAME OF FOREIGN OFFICIAL Drs.J.M.Ebbesen, Henni Lybye, N.O.Bjerregaard		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable

COMMENTS:

18/33 Old product residues were found on rail gates in the main cutting room. The management officials initiated immediate corrective actions, and DVFA officials ordered increased maintenance and pre-operational monitoring.

26 An edible product worker failed to wash his hands and change his gloves after contaminating them through contact with a piece of meat that had fallen onto the floor. The management official ensured that he washed his hands and changed gloves.

28 Several swine heads were observed contacting an inedible container at the station where stick wounds were trimmed. Corrective action by management was immediate.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY	
FOREIGN PLANT REVIEW FORM		4/2/01	47 -- Danish Crown Skive	Skive	
NAME OF REVIEWER Dr. Gary D. Bolstad		NAME OF FOREIGN OFFICIAL Drs. HMEbbesen, ViggoNybyLarsen, CCThorsen		COUNTRY Denmark	
		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/Re-review <input type="checkbox"/> Unacceptable			
CODES (Give an appropriate code for each review item listed below) A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply					
1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	
Temperature control	10 A	Animal identification	37 A	Container closure exam	
Lighting	11 M	Antemortem inspec. procedures	38 A	Interim container handling	
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	
Equipment approval	16 A	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas (inside)	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 A	SSOPs	82 A
Personal hygiene practices	26 A	Ingredients identification	53 O	HACCP	83 A
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O	COMMENTS MADE ON REVERSE	

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE 4/2/01	ESTABLISHMENT NO. AND NAME 47 -- Danish Crown Skive	CITY Skive
	COUNTRY Denmark		
NAME OF REVIEWER Dr. Gary D. Bolstad	NAME OF FOREIGN OFFICIAL Drs. HMEbbesen, ViggoNybyLarsen, CCThorsen	EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	

COMMENTS:

11 Lighting was inadequate (20 foot-candles = fc) at the level of mandibular lymph nodes at the retained-carcass inspection station. During the previous FSIS audit in September 2000, light had been inadequate at many inspection stations, and this had now been corrected at all but the retained-carcass station. Management gave assurances the lighting would be brought up to the required level promptly.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE 4/6/2001	ESTABLISHMENT NO. AND NAME 71 -- Danish Crown Saeby	CITY Saeby
FOREIGN PLANT REVIEW FORM				COUNTRY Denmark
NAME OF REVIEWER Dr. Gary D. Bolstad		NAME OF FOREIGN OFFICIAL Drs. Birgitte Povlsen, Irma Lahmann, Eric Hald		EVALUATION <input type="checkbox"/> Acceptable <input checked="" type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable
CODES (Give an appropriate code for each review item listed below) A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply				
1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations 55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials 56 A
Water potability records	01 A	Product handling and storage	30 M	Laboratory confirmation 57 O
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals 58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims 59 O
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring 60 A
Sanitizers	05 U	Effective maintenance program	33 M	Processing schedules 61 O
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment 62 O
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records 63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection 64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures 65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam 66 O
Lighting	11 M	Antemortem inspec. procedures	38 A	Interim container handling 67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling 68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures 69 O
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant 70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection 71 O
Equipment approval	16 A	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification 72 A
Over-product ceilings	17 M	Returned and rework product	45 A	Inspector verification 73 A
Over-product equipment	18 M	3. RESIDUE CONTROL		Export certificates 74 A
Product contact equipment	19 M	Residue program compliance	46 A	Single standard 75 A
Other product areas (inside)	20 A	Sampling procedures	47 A	Inspection supervision 76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items 77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security 78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification 79 A
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status 80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports 81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	SSOPs 82 M
Personal hygiene practices	26 M	Ingredients identification	53 A	HACCP 83 M
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O	COMMENTS MADE ON REVERSE

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE 4/6/2001	ESTABLISHMENT NO. AND NAME 71 -- Danish Crown Saeby	CITY Saeby
			COUNTRY Denmark
NAME OF REVIEWER Dr. Gary D. Bolstad	NAME OF FOREIGN OFFICIAL Drs. Birgitte Povlsen, Irma Lahmann, Eric Hald		EVALUATION <input type="checkbox"/> Acceptable <input checked="" type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable

COMMENTS:

05 There was no sanitizer in the pre-boning trim area. The DVFA officials ordered immediate correction.

11 Only half the required amount of light was available at inspection surfaces of carcasses on the retained rail. DVFA ordered prompt correction.

17,19 A stack of edible containers, ready for use, was stored under an area of heavy condensation on the ceiling in the corner of one large cutting room. The establishment sent the containers for re-cleaning, but later in the review another piece of equipment used for transporting edible containers was found to be stored in the same location.

18 Heavy condensation was present over a product-flow area at the entrance to the bacon department. The management corrected the situation.

18,33 Heavy rust, flaking paint, and heavy, dried and flaking grease were observed on over-product equipment in the pre-boning trim area. Management officials agreed to clean the area promptly.

26 An edible product worker was observed to contaminate his hands on an inedible container and not wash his hands before returning to work. The DVFA officials took immediate corrective action.

30 Several stainless steel combos were found by the FSIS auditor to have torn plastic covers; other combos had been stacked on some of these. The Veterinarian-In-Charge of the establishment ordered corrections, but neither he nor the management representative took follow-up actions to ensure there were no more; the FSIS auditor looked further and found several others.

82 There was inadequate documentation of operational findings and corrective actions relating to condensation control. DVFA ordered correction.

83 There was inadequate documentation of corrective actions when critical limits for cooler temperatures were exceeded. DVFA ordered correction.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE 3/26/01	ESTABLISHMENT NO. AND NAME 91 -- Koopmann Slagteri		CITY Silkeborg
FOREIGN PLANT REVIEW FORM					COUNTRY Denmark
NAME OF REVIEWER Dr. Gary D. Bolstad		NAME OF FOREIGN OFFICIAL Drs. J.M. Ebbesen, Anna Wolf, Palle Andersen		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	
CODES (Give an appropriate code for each review item listed below) A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply					
1. CONTAMINATION CONTROL		Cross contamination prevention	28 M	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 O
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 M	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 A	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 O
Equipment approval	16 A	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 A	Single standard	75 A
Other product areas (inside)	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 A	SSOPs	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A	HACCP	83 A
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O	COMMENTS MADE ON REVERSE	

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE 3/26/01	ESTABLISHMENT NO. AND NAME 91 -- Koopmann Slagteri	CITY Silkeborg
			COUNTRY Denmark
NAME OF REVIEWER Dr. Gary D. Bolstad	NAME OF FOREIGN OFFICIAL Drs. J.M. Ebbesen, Anna Wolf, Palle Andersen		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable

COMMENTS:

05 Sanitizing facilities for the splitting saws used at the retained inspection area were inadequate. The DV FA official ordered prompt installation of adequate sterilizers. Three sterilizers on the slaughter floor, at trim stations after the post-mortem inspection, were below the required temperatures. The establishment General Director took immediate corrective action.

19/34 Inadequately cleaned plastic containers were ready for use in one production area. Corrective action was taken immediately by the inspection personnel.

28 A floor cleaner contaminated two edible product containers and two hams. The Veterinarian-In-Charge ordered cleaning of the edible product containers and trimming of the contaminated product.

82 There was some documentation identifying a need for increased attention to maintenance of overhead structures (small amounts of rust and flaking paint in some areas, but it was in need of improvement. The problem was adequately identified and addressed by the Danish internal reviewer, and improved maintenance was ordered.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE 4/9/2001	ESTABLISHMENT NO. AND NAME 165 -- Hjørring Frysehus		CITY Hjørring
FOREIGN PLANT REVIEW FORM					COUNTRY Denmark
NAME OF REVIEWER Dr. Gary D. Bolstad		NAME OF FOREIGN OFFICIAL Drs. Birgite Povlsen, Irma Lahmann, Gitte Olesen		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	
CODES (Give an appropriate code for each review item listed below) A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply					
1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 O	Packaging materials	56 O
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 O	Label approvals	58 O
Back siphonage prevention	03 O	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 O
Sanitizers	05 O	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 A	Condemned product control	43 O	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 M	Inspector verification	73 M
Over-product equipment	18 A	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 O	Residue program compliance	46 O	Single standard	75 A
Other product areas (inside)	20 A	Sampling procedures	47 O	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	SSOPs	82 A
Personal hygiene practices	26 A	Ingredients identification	53 O	HACCP	83 O
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O	COMMENTS MADE ON REVERSE	

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE 4/9/2001	ESTABLISHMENT NO. AND NAME 165 -- Hjørring Frysehus	CITY Hjørring
	COUNTRY Denmark		
NAME OF REVIEWER Dr. Gary D. Bolstad	NAME OF FOREIGN OFFICIAL Drs. Birgite Povlsen, Irma Lahmann, Gitte Olesen	EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	

COMMENTS:

45 The protocol for the handling of damaged cartons was not adequately described in the establishment's documentation. (Cartons that arrived damaged or that were damaged on the premises with the contents exposed were returned to the establishment of origin for reinspection and repackaging; less damaged cartons with no product exposed were either repaired or the lids replaced and the original labels affixed to the new lids. The DVFA reviewer ordered updated documentation of the procedures.

73 The veterinarian responsible for the oversight of the facility was not adequately documenting her routine circuit visits, except for the monthly supervisory reports. The DVFA reviewer ordered correction.

5, 13, 19, 22, 27, 29, 31, 37-48, 51-71, 80, 83 NOTE: This is a cold store facility only.

Att. F-8a

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE 3/20/01	ESTABLISHMENT NO. AND NAME 190 -- Frysehus Aabenraa		CITY Aabenraa
FOREIGN PLANT REVIEW FORM					COUNTRY Denmark
NAME OF REVIEWER Dr. Gary D. Bolstad		NAME OF FOREIGN OFFICIAL Dr. Henning Petersen, Dr. Olaf Nommensen		EVALUATION <input type="checkbox"/> Acceptable <input checked="" type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	
CODES (Give an appropriate code for each review item listed below) A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply					
1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 M	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 M	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 U	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 M	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 O
Pest --no evidence	07 M	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 A	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 M	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 O	Single standard	75 A
Other product areas (inside)	20 A	Sampling procedures	47 O	Inspection supervision	76 M
Dry storage areas	21 M	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	SSOPs	82 A
Personal hygiene practices	26 M	Ingredients identification	53 O	HACCP	83 M
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O	COMMENTS MADE ON REVERSE	

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE 3/20/01	ESTABLISHMENT NO. AND NAME 190 -- Frysehus Aabenraa	CITY Aabenraa
			COUNTRY Denmark
NAME OF REVIEWER Dr. Gary D. Bolstad	NAME OF FOREIGN OFFICIAL Dr. Henning Petersen, Dr. Olaf Nommensen	EVALUATION <input type="checkbox"/> Acceptable <input checked="" type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	

COMMENTS:

7/21/33 Dead insects and spider webs were in evidence on slanting windowsills above stored packaging materials. The management official ordered the room to be thoroughly cleaned before the next day's production.

18/30/33 Rust was present on overhead structures in a cooler, with exposed product stored directly underneath. Cleaning and painting were scheduled and measures were put in place to prevent storage of product under the area in question.

19/35 An obvious grease spot on a cutting board was ignored by a worker returning from a break. DVFA officials ordered immediate cleaning and disinfection.

19/33 Approximately one-fourth of the stainless steel combo bins in use were cracked and torn. The establishment manager expressed the opinion that they were acceptable for general use. DVFA officials ordered repair or replacement.

26 Three workers did not wash their hands in the boning room when returning from a break. Another worker hung his apron on a wall hook intended for storage of, and in contact with, a shovel used for meat that had fallen on the floor. The establishment official took immediate corrective actions.

29/31 The dropped meat reconditioning procedure, as demonstrated, was unacceptable, resulting in gross contamination of the meat to be trimmed and of the work surface on which the procedure was performed. The knife was not sanitized after being contaminated. The internal reviewer who was leading the audit stopped the procedure and the meat was condemned.

83 The establishment management had developed no procedures to verify that the HACCP plan was being effectively implemented and functioning as designed. No pre-shipment document review program had been developed or implemented.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE 4/3/01	ESTABLISHMENT NO. AND NAME 339 -- Danish Crown Hurup		CITY Hurup
FOREIGN PLANT REVIEW FORM					COUNTRY Denmark
NAME OF REVIEWER Dr. Gary D. Bolstad		NAME OF FOREIGN OFFICIAL Drs. HMEbbesen, ViggoNybyLarsen, CCThorsen		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	
CODES (Give an appropriate code for each review item listed below) A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply					
1. CONTAMINATION CONTROL		Cross contamination prevention	28 M	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 O	Special label claims	59 O
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 A	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 O	Inspector verification	73 A
Over-product equipment	18 A	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas (inside)	20 A	Sampling procedures	47 O	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	SSOPs	81 A
Personal hygiene practices	26 A	Ingredients identification	53 O	HACCP	83 A
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O	COMMENTS MADE ON REVERSE	

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE 4/3/01	ESTABLISHMENT NO. AND NAME 339 -- Danish Crown Hurup	CITY Hurup
			COUNTRY Denmark
NAME OF REVIEWER Dr. Gary D. Bolstad	NAME OF FOREIGN OFFICIAL Drs. HMEbbesen, ViggoNybyLarsen, CCThorsen		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable

COMMENTS:

28 Several workers were observed to contaminate their aprons through contact with an inedible container in the receiving area. DVFA officials took immediate corrective actions.



Food Safety and Inspection Service
International Policy Division
Att: Sally Stratmoen, Acting Director
USDA
Washington, D.C. 20250-3700
USA

Date: 21 September 2001

Our ref.: HP/-

File: FA 3370-29/01

please note when replying

By fax 202- 720- 7990

Dear Sally Stratmoen

Re.: Draft Audit report for Denmark 2001.

By letter of July 26, 2001, you have forwarded a draft audit report for the on-site audit of Denmark's meat inspection system, conducted from March 14 to April 10 2001. The report was received on August 1, 2001.

You have invited the Danish Veterinary and Food Administration to provide comments regarding the information in the report within 60 days of the receipt of the report.

The Danish Veterinary and Food Administration (DVFA) hereby wish to express its recognition of the report, with the exception of the following remarks:

Page 3: Entrance meeting.

The meeting was held on 14 March 2001. ✓

Regarding the participants, please delete the following persons: ✓

Dr. Kristian Hermansen, Dr. Justin Ajufo, Dr. Mette Hjulmand-Lassen, Mr. Finn Haunstrup Clemmensen, Dr. Mette Espersen. ✓

Please add the following person: Susanne J. Jensen, Food Scientist. ✓

Page 9, Dry Storage Areas, point 2:

DVFA presume that the establishment number in question is 190.

The USDA audit officer has recommended a re-review of the establishments 71 and 190. DVFA hereby inform, that re-reviews has been carried out. The reviews showed that appropriate actions have been taken. However, the condensation problems at est. no. 71 are not yet fully solved. The necessary temporary measures are taken, and a permanent solution will be established before December 2001.

Please find enclosed report of 13 September 2001 from the Chief Veterinarian at est. no 71, Eric Hald, and report of 19 September 2001 from Veterinarian (Audit Officer) Olaf Nommensen, regarding est. no. 190.

Yours sincerely

A handwritten signature in black ink, appearing to read 'B. Povlsen', with a long horizontal stroke extending to the left.

Dr. Birgitte Povlsen
Senior Veterinary Officer
Head of Import-Export Division
Food Department

copy: Embassy of USA, Copenhagen, Denmark.